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103D CONGRESS
1ST SESSION

H. R. 2923

To amend the Federal Food, Drug, and Cosmetic Act to revise the regulation of dietary supplements.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 6, 1993

Mrs. COLLINS of Illinois introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to revise the regulation of dietary supplements.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; REFERENCE.

This Act may be cited as the ''Dietary Supplement Consumer Protection Act of 1993''.

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act

SEC. 2. DEFINITIONS.

Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

''(gg) The term 'dietary supplement' means an article that is—

''(1) intended to supplement the diet,

''(2) is, or contains, a vitamin, mineral, or an herb or similar nutritional substance, including a concentrate or extract of a vitamin, mineral, or other nutritional substance, and

''(3)(A) is intended for ingestion in a form described in paragraph (1)(B)(i) or (2) of section 411(c) or in another similar form, or

''(B) complies with section 411(c)(1)(B)(ii).

''(hh) The term 'dietary ingredient' means a vitamin, mineral, or herb or other similar nutritional substance the intended use of which results, or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any dietary supplement.''.

SEC. 3. DEFINITIONS AND STANDARDS OF IDENTITY.

Section 401 (21 U.S.C. 341) is amended—

(1) in the first sentence, by inserting ''or dietary supplement'' after ''establishing for any food'', and

(2) in the fourth sentence, by inserting ''or dietary supplement'' after ''any food'' and by inserting ''or dietary supplements'' after ''class of food''.

SEC. 4. ADULTERATION.

Section 402 (21 U.S.C. 342) is amended—

(1) by inserting ''or dietary supplement'' after ''food'' before paragraph (a), and

(2) by adding at the end the following:

''(f) If it is a dietary supplement and it is, or contains, any dietary ingredient which is unsafe within the meaning of section 413.

''(g) If it is a dietary supplement and it does not meet the quality factor requirements prescribed by the Secretary under this paragraph. The Secretary shall, by regulation, establish requirements for quality factors for dietary supplements as appropriate.

''(h)(1) If it is a dietary supplement and the processing of such dietary supplement is not in compliance with the good manufacturing practices and the quality control procedures established by the Secretary under subparagraph (2).

''(2) The Secretary shall, by regulation, establish good manufacturing practices for dietary supplements, including quality control procedures that the Secretary de-

termines are necessary to assure that a dietary supplement—

''(A) provides the vitamin, mineral, or herb or other nutritional substance it claims to provide in its label or labeling, and

''(B) is manufactured in a manner designed to prevent adulteration.''.

SEC. 5. MISBRANDING.

Section 403 (21 U.S.C. 343) is amended—

(1) by inserting ''or dietary supplement'' after ''food'' before paragraph (a),

(2) in paragraph (a)(2), by inserting ''or dietary supplement'' after ''food'',

(3) in paragraph (b), by inserting ''or dietary supplement'' after ''another food'',

(4) in paragraph (g), by inserting ''or dietary supplement'' after ''food'' each place it occurs,

(5) in paragraph (h), by inserting ''or dietary supplement'' after ''food'' each place it occurs,

(6) in paragraph (i)(1), by inserting ''or dietary supplement'' after ''food'',

(7) in paragraph (r)(1), by inserting ''or dietary supplement'' after ''food'' each place it occurs and by inserting ''or dietary ingredient'' after ''nutrient'' each place it occurs,

(8) in paragraph (r)(1)(B), by inserting ''or any dietary supplement'' after ''food'' and by striking out ''or (5)(D)'',

(9) in paragraph (r)(3)(A)(ii), by inserting ''or dietary supplement'' after ''food'' each place it occurs and by inserting ''or dietary ingredient'' after ''nutrient'',

(10) in paragraph (r)(3)(B)(ii)(I), by inserting ''or dietary supplements'' after ''food'' and by inserting ''or dietary ingredient'' after ''(q)(2)'',

(11) in paragraph (r)(3)(B)(ii)(II), by inserting ''or dietary ingredient'' after ''nutrient'',

(12) in paragraph (r)(5), by striking out clause (D), and

(13) by adding at the end the following:

''(s) If it is a dietary supplement, unless its label and labeling contain the date after which it should no longer be consumed as prescribed by the Secretary by regulation.

''(t) If it is a dietary supplement, unless its label and labeling contain, where appropriate, a statement regarding possible adverse effects as prescribed by the Secretary by regulation. Such a statement shall indicate the level, if any, at which a dietary supplement can cause adverse effects and the specific nature of any adverse effects and

shall identify segments of the population, including the elderly and children, that may be affected.''.

SEC. 6. SAFETY PROVISIONS AND NOTIFICATION REQUIREMENTS FOR DIETARY INGREDIENTS.

Subchapter IV of chapter 4 is amended by adding at the end the following:

''DIETARY INGREDIENTS SAFETY

''SEC. 413. (a) A dietary ingredient shall, with respect to any particular or intended use of such ingredient, be deemed unsafe for the purposes of section 402(f) unless—

''(1) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such dietary ingredient may be safely used,

''(2) such ingredient is generally recognized, among experts qualified by adequate training and experience to evaluate its safety, as having been adequately shown through scientific procedures to be safe under the conditions of its intended use, or

''(3) in the case of a dietary ingredient in use in a dietary supplement before August 5, 1993, it has been adequately shown, through either scientific procedures or experience based on common use in a dietary supplement, to be safe under the conditions

of its intended use pending completion of the review required by subsection (f).

''(b) Any person may with respect to any intended use of a dietary ingredient file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such ingredient may be safely used. The Secretary shall by regulation establish requirements for petitions submitted under this subsection.

''(c) The Secretary shall by order—

''(1) establish a regulation (whether or not in accord with the regulation proposed by the petitioner) prescribing, with respect to one or more proposed uses of the dietary ingredient involved, the conditions under which such ingredient may be safely used, including specifications as to the—

''(A) particular dietary supplement or classes of dietary supplements in which such ingredient may be used,

''(B) the maximum quantity which may be used or permitted in the dietary supplement,

''(C) the manner in which such ingredient may be added to or used in the dietary supplement, and

''(D) any directions or other labeling or packaging requirements for such ingredient

deemed necessary by the Secretary to assure the safety of its use, and

notify the petitioner of such order and the reasons for it, or

''(2) deny the petition and notify the petitioner of such order and the reasons for it.

''(d) The Secretary may at any time, upon the Secretary's own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a dietary ingredient, the conditions under which such ingredient may be safely used and the reasons therefor.

''(e) Each person who proposes to begin the introduction or delivery into interstate commerce of a dietary ingredient that it determines to be subject to subsection (a)(2) shall, at least 90 days before making such introduction or delivery, notify the Secretary, in such form and manner as the Secretary shall by regulation prescribe, of such introduction or delivery.

''(f) The Secretary shall commence a safety review of those dietary ingredients subject to subsection (a)(3) within 60 days of the date of the enactment of this section.''.

''NOTIFICATION

''SEC. 414. If the manufacturer, distributor, or retailer of a dietary supplement or ingredient has knowledge which reasonably supports the conclusion that a dietary

supplement or ingredient may be adulterated or misbranded, such manufacturer, distributor, or retailer shall promptly notify the Secretary of such knowledge.''.

SEC. 7. ADVISORY COMMITTEE.

The Secretary of Health and Human Services shall establish an advisory committee, in accordance with the Federal Advisory Committee Act, to assist in the implementation of the amendments made by this Act.

SEC. 8. RESEARCH.

(a) ESTABLISHMENT.—The Director of the National Institutes of Health shall expand and intensify programs with respect to research and related activities regarding dietary supplements.

(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out subsection (a), there are authorized to be appropriated $10,000,000 for fiscal year 1994 and such sums as may be necessary for each of the fiscal years 1995 through 1997.

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